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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/542,386

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Roni Zvuloni

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EXAMINER

BOR, HELENE CATHERINE

ART UNIT

PAPER NUMBER

3768

MAIL DATE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/542,386	Applicant(s) ZVULONI, RONI	
	Examiner HELENE BOR	Art Unit 3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 July 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,6-33 and 35-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,6-33 and 35-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 October 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Applicant uses the claim language, "a plurality of said plurality of strain gauges". The Examiner contends this claim language is confusing and fails to clearly define what the Applicant intends to claim. The Examiner suggests replacing this language with the claim language used in Claim 35, "a plurality of sets of strain gauges" or delete "a plurality of", which ever better defines the meaning of the intended language.

Claim Rejections - 35 USC § 102

4. Claim 1-3, & 5-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Murphy (US Patent No. 5,902,308).

Claim 1: Murphy teaches a balloon catheter (Figure 5, Element 60) comprising a plurality of conductor bands [strain gauges] which vary in electrical resistance with the balloon circumference (Col. 5, Line 59-60 & Col. 9, Line 12-14).

Art Unit: 3768

Claim 2 & 3: Murphy teaches the conductor bands are mounted internally to the balloon wall (Col. 9, Line 30-32). Murphy also teaches a sensor capable of being attached to the external surface of the balloon (Col. 5, Line 40).

Claim 5 & 6: Murphy teaches the plurality of conductor bands mounted in a circumferential configuration (Figure 5, Element 62) and mounted in a plurality of circumferential configuration (Figure 5, Element 62).

Claim 7: Murphy teaches the radio-opaque markers (Col. 5, Line 52-65 & Col. 8, Line 49-54).

Claim 8 & 10: Murphy teaches an ultrasound marker distinguishable under ultrasound imaging (Col. 5, Line 52-60) and teaches the radio-opaque markers (Col. 5, Line 52-65 & Col. 8, Line 49-54). Murphy teaches the asymmetric configuration of the markers (Figure 11, Element 124).

Claim 9: Murphy teaches an ultrasound marker distinguishable under ultrasound imaging (Col. 5, Line 52-60).

Claim 11: Murphy teaches the conductor bands having a wire connection (Col. 6, Line 66).

Claim Rejections - 35 USC § 103

5. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Murphy (US Patent No. 5,902,308) as applied to claim 1-3, & 5-11 above, and further in view of Knowlton et al. (US Patent No. 6,427,089).

Claim 4: Murphy does not teach the sensor being embedded the in the balloon wall. However, Knowlton teaches a sensor being embedded in the balloon wall (Col. 15, Line

Art Unit: 3768

6-10) as an alternate equivalent manner to connect the wall and sensor. Thus it would have been obvious to one of ordinary skill in the art to modify the system of Murphy by including the wall sensor being embedded in the balloon as taught by Knowlton as alternate equivalent manner to connect the wall and sensor.

6. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Murphy (US Patent No. 5,902,308) as applied to claim 1-3, & 5-11 above, and further in view of Holmes et al. (US Patent No. 4,873,990).

Claim 12: Murphy teaches the conductor bands having a wire connection (Col. 6, Line 66). Murphy fails to teach a wireless connection used by the conductor bands for reporting. However, Holmes teaches a device wherein the strain gauges are operable to report strain through telemetry [wireless connection] (Col. 4, Line 30-36) in order to provide information to remote equipment for monitoring (Col. 4, Line 38-36). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system of Murphy to include the wireless connection as taught by Holmes in order to provide information to remote equipment for monitoring (Col. 4, Line 38-36).

7. Claim 13-17, 19-22, 27-29, 31-32 & 35-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Murphy (US Patent No. 5,902,308), and further in view of Houser (US Patent No. 5,865,801).

Claim 13-14, 20-22 & 27-29: Murphy teaches a balloon catheter (Figure 5, Element 60) comprising a plurality of conductor bands [strain gauges] which vary in electrical resistance with the balloon circumference (Col. 5, Line 59-60 & Col. 9, Line 12-14). Murphy teaches displaying ultrasound and fluoroscope images (Col. 5, Line 54-56).

Art Unit: 3768

Murphy teaches expanding a balloon within a blood vessel (Col. 3, Line 60-63). Murphy teaches the device is very useful in the measurement of vascular stenoses [obstructions] (Col. 5, Line 51-52). Stenosis is being defined as “narrowing of a normal passage” or analogs to an obstruction. Murphy teaches conductor bands to provide information on the balloon cross-section in more than one target location (Col. 9, Line 30-35). Thus the method as taught by Murphy can report less expansion in local portions of the balloon by the conductor bands. Murphy fails to teach the data analysis aspect of the invention such as comparing the expansions reported by the conductor bands or recording the data in a memory module. However, Houser also teaches a method of data analysis as the comparing measured parameters reported by a plurality of sensors and recording the data in a memory module [control center] (Col. 7, Line 62-65 & Figure 11, Element 107) to monitor the relationship between the balloon and artery tissue allowing the catheter to be adaptable to treat different plaque hardness and to avoid overinflation (Col. 1, Line 66 – Col. 2, Line 4). It would have been obvious to one of ordinary skill in the art to modify the system of Murphy to include the data analysis as taught by Houser to monitor the relationship between the balloon and artery tissue allowing the catheter to be adaptable to treat different plaque hardness and to avoid overinflation (Col. 1, Line 66 – Col. 2, Line 4).

Claim 19 & 35: Murphy teaches that multiple resistors may be used to provide information on balloon cross-section in more than one target location. Murphy fails to teach the multiple circumferential positions around a common circumference. However, Houser teaches this configuration (Figure 3, Element 5) to monitor the relationship

Art Unit: 3768

between the balloon and artery tissue allowing the catheter to be adaptable to treat different plaque hardness and to avoid overinflation (Col. 1, Line 66 – Col. 2, Line 4). It would have been obvious to one of ordinary skill in the art to modify the strain gauge of Murphy to include the multiple circumferential positions around a common circumference as taught by Houser in order to monitor the relationship between the balloon and artery tissue allowing the catheter to be adaptable to treat different plaque hardness and to avoid overinflation (Col. 1, Line 66 – Col. 2, Line 4).

Claim 15-17 & 36-39: Murphy teaches the radio-opaque markers (Col. 5, Line 52-65 & Col. 8, Line 49-54) and observing the balloon by fluoroscopy [x-ray] (Col. 5, Line 17-21). Murphy teaches an ultrasound marker distinguishable under ultrasound imaging (Col. 5, Line 52-60) and observing the balloon by ultrasound (Col. 5, Line 17-21). Murphy teaches the asymmetric configuration of the markers (Figure 11, Element 124).

Claim 31-32: Murphy teaches the conductor bands are mounted internally to the balloon wall (Col. 9, Line 30-32). Murphy also teaches a sensor capable of being attached to the external surface of the balloon (Col. 5, Line 40).

Claim 40: Murphy teaches the conductor bands having a wire connection (Col. 6, Line 66).

8. Claim 18, 23-26 & 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Murphy (US Patent No. 5,902,308) and Houser (US Patent No. 5,865,801) as applied to claim 13-17, 19-22, 27-29, 31-32 & 35-40 above, and further in view of Strommer'548 et al. (US Patent Application No. 2004/0138548).

Art Unit: 3768

Claim 18, 23-26 & 30: Murphy teaches imaging techniques such as ultrasound and fluoroscopy (Col. 5, Line 55-56). Further, Houser generating the two images one from the transducers on the balloon and then using radiopaque markers [x-ray imaging] to assist the physician in positioning the balloon in the occluded area (Col. 9, Line 15-21). Murphy and Houser fail to teach to teach image integration of the images. However, Strommer teaches integration of two images from two different imaging modalities (Abstract & Page 2, Para 0013). It would have been obvious to one of ordinary skill in the art to modify the system of Murphy and Houser to include the image combining as taught by Strommer in order to view the location and orientation of the medical intervention device (e.g., catheter, needle) within the body of the patient during the operation (Page 1, Para 0002).

9. Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Murphy (US Patent No. 5,902,308) and Houser (US Patent No. 5,865,801) as applied to claim 13-17, 19-22, 27-29, 31-32 & 35-40 above, and further in view of Knowlton et al. (US Patent No. 6,427,089).

Claim 33: Murphy does not teach the sensor being embedded the in the balloon wall. However, Knowlton teaches a sensor being embedded in the balloon wall (Col. 15, Line 6-10) as an alternate equivalent manner to connect the wall and sensor. Thus it would have been obvious to one of ordinary skill in the art to modify the system of Murphy and Houser by including the wall sensor being embedded in the balloon as taught by Knowlton as alternate equivalent manner to connect the wall and sensor.

Art Unit: 3768

10. Claim 41 is rejected under 35 U.S.C. 103(a) as being unpatentable over Murphy (US Patent No. 5,902,308) and Houser (US Patent No. 5,865,801) as applied to claim 13-17, 19-22, 27-29, 31-32 & 35-40 above, and further in view of Holmes et al. (US Patent No. 4,873,990).

Claim 41: Murphy teaches the conductor bands having a wire connection (Col. 6, Line 66). Murphy fails to teach a wireless connection used by the conductor bands for reporting. However, Holmes teaches a device wherein the strain gauges are operable to report strain through telemetry [wireless connection] (Col. 4, Line 30-36) in order to provide information to remote equipment for monitoring (Col. 4, Line 38-36). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system of Murphy and Houser to include the wireless connection as taught by Holmes in order to provide information to remote equipment for monitoring (Col. 4, Line 38-36).

Response to Arguments

Applicant's arguments filed 07/08/2008 have been fully considered but they are not persuasive. The Examiner interpreted the Applicant's Remarks as asserting that the amended claims were amended to claim a plurality of strain gauges arranged around a common circumference position as shown in Figure 2b of Applicant's Drawings. In regards to the rejection under 35 102 U.S.C 102(b), the Examiner contends the reference is still applicable. Contrary to the Applicant's assertions, the claim language does not clearly define the structural relationship in the manner that the Applicant argues that the claimed language is directed to. Thus, the claims are still broad enough

Art Unit: 3768

to be interpreted as being read on by Murphy (US Patent No. 5,902,308). The Examiner contends that “at different circumferential positions” and “plurality of said plurality of strain gauges” does not necessarily mean the configuration of the strain gauges that the Applicant is making the argument for in the Applicant’s Remarks. The claimed “circumferential positions” is not set forth to have a defined structural relationship with the balloon and as such, a reasonable interpretation of the claim language includes an arrangement having the circumference traced along (parallel with) the longitudinal axis of the balloon. With such an interpretation, it is reasonable to conclude Murphy still reads on the claimed matter. The rejection of claims 1-3 & 5-12 under 35 U.S.C. § 102 rejection is hereby maintained.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

Art Unit: 3768

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Helene Bor whose telephone number is 571-272-2947. The examiner can normally be reached on M-T 8:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. B./
Examiner, Art Unit 3768

/Eric F Winakur/
Primary Examiner, Art Unit 3768